

(19) World Intellectual Property  
Organization  
International Bureau



08 DEC 2004



(43) International Publication Date  
21 May 2004 (21.05.2004)

PCT

(10) International Publication Number  
**WO 2004/041253 A1**

(51) International Patent Classification<sup>7</sup>: **A61K 9/16**,  
31/427, 31/472

(74) Agents: **ALBRECHT, Thomas et al.**; KRAUS & WEIS-  
ERT, Thomas-Wimmer-Ring 15, 85039 München (DE).

(21) International Application Number:  
PCT/EP2003/011949

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE,  
GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,  
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,  
MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,  
RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,  
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date: 28 October 2003 (28.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
02025006.4 8 November 2002 (08.11.2002) EP

(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,  
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,  
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,  
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): **PARI  
GMBH** [DE/DE]; Spezialisten für effektive Inhalation,  
Moosstr. 9, 82319 Starnberg (DE).

**Published:**

— with international search report

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **LINTZ,**  
**Frank-Christophe** [DE/DE]; Waldspielplatz 5, 82319  
Starnberg (DE). **KELLER, Manfred** [DE/DE]; Hegegasse  
5, 79189 Bad Krozingen (DE).

*For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

(54) Title: **WET GRANULATION PROCESS**

(57) **Abstract:** The invention is in the field of pharmaceutical dosage forms, and more particularly in the field of pharmaceutical granules and processes for making granules. The invention provides a process for preparing pharmaceutical granules which contain an active ingredient in the form of a salt, said process comprising the steps of (a) providing a powder containing the active ingredient as a free base or acid, and (b) agglomerating the powder by adding a granulation liquid to form granules; wherein step (b) is conducted in the presence of a neutralization agent capable of neutralizing the active ingredient, and for a sufficient amount of time to allow the active ingredient to become at least partially converted into a salt. The invention also provides pharmaceutical granules obtainable by said process and pharmaceutical compositions comprising said granules. The invention further provides the use of pharmaceutical granules for the pulmonary delivery of an active ingredient.

WO 2004/041253 A1